K121996

# Special 510(k) Summary

AUG 3 2012

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, and Part 807, Title 21 of the Code of Federal Regulations, EB Neuro, S.p.A. submits the following information as premarket notification:

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

## 807.92(a)(1), Submitter Information

EB Neuro, S.p.A.
Via Pietro Fanfani 97/a
Florence, Italy

Contact Person: Allison Scott, RAC
Consultant, Anson Group
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Date: July 6, 2012

## 807.92(a)(2), Name of the Device

Trade Name: BE Plus LTM/GWi

Common Name: Physiological Signal Amplifier

Device Classification Name: Physiological Signal Amplifier

Product Code: GWL

Device Classification Number: 21 CFR 882.1835

Regulatory Status: Class II

## 807.92(a)(3), Predicate Device(s)

| 510(k) Number | Device Name | Submitter Name |
|---|---|---|
| K053606 | BE Plus/Aura LTM 64 Amplifier | EB Neuro, S.p.A. |
| | | |

## 807.92 (a)(4), Device Description

The BE Plus LTM / GWi amplifiers system, which has 64 channels, is an amplifier system which collects the bioelectric signals from the surface of the human body trough appropriate electrodes or sensors, intensify the very low signal captured (typically the amplitude range is of the order of the μVolts), condition them (filtering), convert them in numeric form and pass these data to the "host" elaboration unit (Personal Computer or equivalent system).

For these reason this device is not intended for a "direct" use by the physician but rather by a "manufacturer" or "System Builder" (a company or a researcher) which wants to build a "complete" medical device using the "BE Plus LTM / GWi" amplifier device as the "acquiring part" of the whole system.

BE Plus LTM / GWi is therefore intended to be assembled into an electromedical system by a System Builder, who will define the specific intended use of the assembled medical device.

## 807.92(a)(5), Intended Use(s)

The BE Plus LTM / GWi Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

## 807.92(a)(6), Technological Characteristics

EBNeuro amplifier systems are composed of the following "subsystems":

1. the amplifier box itself (analog conditioning, A/D conversion)
2. the host PC interface (host communication – isolation from PC hardware)
3. the power supply subsystem
4. Optionally a flash led visual stimulator (routinely used during an EEG recording)
5. Optionally an external pulse oximeter module

Both the BE Plus LTM / GWi Amplifier and the predicate device, BE Plus/Aura LTM 64 Amplifier have the same number and type of Channels. The analog channels of the BE Plus LTM/GWi system are the same number and are a slightly upgraded version of those of the predicate device. All devices use one common electrode reference to establish a patient ground (not earth ground) against which all other electrical inputs are referenced. Each device measures values and waveforms and contains many of the same channels of information. All devices detect electrical signals which are then converted to digital data. None of the systems actually deliver energy to the patient, they receive signals from the patient, amplify and filter these signals, and record the digital data derived from the signals. The host communication protocol of the BE Plus LTM/GWi system is substantially the same of the predicate device. Both systems provide the option of the same EBNeuro Flash Led stimulator. Both devices provide the capability to store "internally" the acquired data when the host connection is not operating and the capability to transfer these data in a delayed time when connection should be restored. Both devices use the same AC/DC adapter.

Both the BE Plus LTM / GWi Amplifier and the predicate device, BE Plus/Aura LTM 64 Amplifier can be powered by an external IEC 60601-1 compliant Mains Adapter, the BE Plus LTM/Gwi can also operate with an internal rechargeable battery pack. The BE Plus LTM/GWi system provides the option of a Pulse Oximeter Module, based on the Nonin OEM III module cleared under K093728 (EBNeuro BE micro/Trea device). While both Amplifier can be connected to the host computer by means of a "wired" LAN cable, the BE Plus LTM/GWi can be connected to the host in a "wireless" mode (WLAN/IEEE 802.11).

## 807.92(b)(1), Non-Clinical Performance Data

The verification and validation (V&V) plan including definition of test methods and acceptance criteria were designed to ensure equivalent performance with the predicate device. The verification included software unit testing, integration testing and software system testing with functional testing of all software requirements. The validation process was performed to ensure that the system meets the user needs specification. The V&V test results showed that the BE Plus LTM / GWi Amplifier meets its intended use, user needs and software requirements. Additional testing was performed to verify the performance of wireless function, wireless coexistence and quality of service, the integrity and security of wirelessly transmitted data and of access to the wireless network, and electromagnetic compatibility.

## 807.92(b)(2), Clinical Performance Data

Clinical testing was not conducted to support this 510(k) submission.

## 807.92(b)(3), Non-Clinical and Clinical Performance Data Conclusions

The non-clinical performance data concludes that the subject device has equal performance and raises no new questions of safety and effectiveness in comparison to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 3 2012

EB Neuro S.p.A.
c/o Ms. Allison Scott, RAC
Anson Group
9001 Wesleyan Road, Suite 200
Indianapolis, IN 46268

Re: K121996
Trade/Device Name: BE Plus LTM/GWi Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: July 6, 2012
Received: July 9, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K121996

Device Name: BE Plus LTM / GWi

Indications for Use:

The BE Plus LTM / GWi Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

XIAORUI TANG

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121996